



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/642,772 | 08/18/2003 | Meir Rosenberg | 022719-0046 | 3663 |

21125 7590 01/29/2007
NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

| |
|----------|
| EXAMINER |
|----------|

HOEKSTRA, JEFFREY GERBEN

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/29/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/642,772 | Applicant(s) ROSENBERG, MEIR | |
| | Examiner Jeffrey G. Hoekstra | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-11, 13, and 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (US 5,291,896) in view of Purdy et al (US 2003/0097082 A1).

4. For claims 1 and 18, Fonger et al discloses a catheter drainage system as broadly as *structurally* claimed, comprising: an elongated tube, or catheter, 12 including a distally disposed solid state pressure transducing sensor 14 (column 6 lines 1-41) as best seen in Figures 1 and 2 and (b) said sensor *functions* to measure pressure adjacent the external surface of the distal-most end of the catheter (column 5 lines 4-20

Art Unit: 3736

and column 6 lines 1-41), further including at least one wire 24 distally coupled to the sensor and proximally mated to an apparatus for electrical powering or communicating that extends along the length of the catheter in fluid isolation from the inner lumen 40 and wherein the at least one wire being proximally separable from the elongated tube through a slit 46 such that the tube length is selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44)). Furthermore, the slit 46 extends through the outer wall 15 of the tube 12 into the second lumen 42 such that the at least one wire can be partially removed to adjust the tube length.

5. For claims 2 and 11, Fonger et al discloses the at least one wire 24 disposed within a second lumen 42 isolated from the first and wherein the slit 46 extends into the second lumen).

6. For claim 3, 6-10, and 21-24, Fonger et al discloses a slit 46 extending through the outer wall 15 of the tube 12 into the second lumen 42 such that the tube length is selectively adjustable (column 4 lines 32-44). The slit 46 is configured such that the at least one wire can be partially removed to adjust the tube length and when said wire(s) is/are inserted they are in substantial fluid isolation via the sealing action of the polymer. The slit 46 is configured (column 4 lines 6-10) to extend along a distance less than the length of the catheter and less than about one half the length of the catheter as best seen in Figure 1.

7. For claims 4 and 19, Fonger et al discloses a first lumen diameter greater than the second lumen diameter (column 3 lines 60-66).

Art Unit: 3736

8. For claims 5 and 20, Fonger et al discloses multiple secondary lumens 84,86,88,90 formed within an invagination of the outer tube wall 12 as best seen in Figure 7.

9. For claims 13 and 25, Fonger et al discloses the use of a flexible, biocompatible polymer (column 3 lines 41-42).

10. For claims 15-17 and 26-27, Fonger et al discloses a distally disposed pressure sensor (column 6 lines 13-18) adapted to sense physiological conditions adjacent to the elongated tube and disposed within the secondary lumen with an inner diameter of 10 French (column 3 lines 63-66) which is equal to approximately 3.3 mm or 0.131 inches.

11. Fonger et al discloses the claimed invention except for explicitly disclosing (a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna. Purdy et al teaches (a) a distally disposed pressure sensor (94) embedded in a distal portion of the catheter as best seen in Figure 14, 15, and 17 (paragraph 132) and (b) at least one wire having a proximal end mated to an external antenna (wire element 96, paragraph 133).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pressure-measuring trimmable sensing catheter as taught by Fonger et al, with embedded pressure sensor and antenna as taught by Purdy et al for the purpose increasing the efficacy of a pressure measurement device and increasing patient safety during advanced medical procedures requiring pressure management whilst draining fluid.

Art Unit: 3736

12. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al and in further view of Quackenbush (US 5,104,398). Fonger et al in view of Purdy et al discloses the claimed sensor catheter drainage system except for (a) the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and (b) the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter. Quackenbush discloses a membrane splitting tube 10 comprised of polyurethane (column 3 line 23) with a catheter or wire inserted in an outer peel-away membrane (column 1 lines 33-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trimmable sensing catheter as taught by Fonger et al in view of Purdy et al, with the polyurethane splitting tube of Quackenbush for the purpose of configuring an implantable fluid management device, including a catheter having at least one wire running there through, which is coupled to a sensor disposed at a distal portion of the catheter, for use in advanced medical procedures requiring pressure management whilst draining fluid.

Response to Arguments

13. Applicant's arguments filed 11/15/2006 have been fully considered but they are not persuasive. Applicant argues (1) the rejection of claims 1-11, 13, and 15-27 under 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Purdy et al and (2) the rejection of claims 12 and 14 under 35 U.S.C. 103(a) as being unpatentable over

Art Unit: 3736

Fonger et al in view of Purdy et al and in further view of Quackenbush. Specifically, regarding (1) applicant argues there is no motivation to combine the disclosure of Fonger et al with the teachings of Purdy et al because such a modification would changes the principle operation of the reference and there is no motivation to modify the device of Fonger with the teachings of Purdy because there is no expected beneficial result. Specifically, regarding (2) applicant argues Quackenbush does not provide supplemental motivation.

14. In response to applicant's argument that (1) there is no motivation to combine the references because such a modification would changes the principle operation of the reference, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

15. In response to applicant's argument (1) and (2) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

Art Unit: 3736

Fonger, Purdy, and Quackenbush all teach implantable fluid management devices (i.e. medical catheters) and methods of use thereof.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

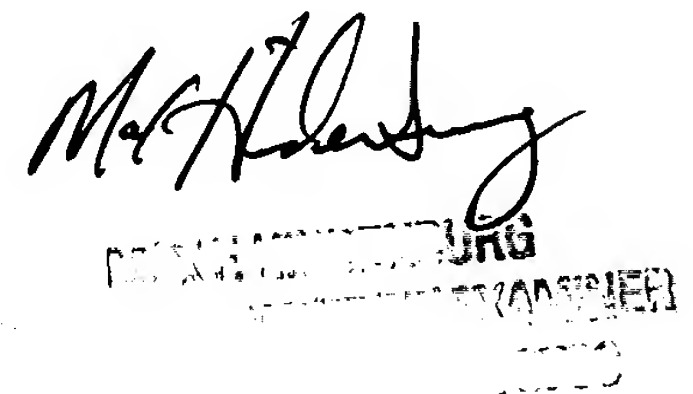
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH



RECEIVED
JAN 11 2011
USPTO